

**REMARKS**

Review and reconsideration of the Second Office Action of August 10, 2005, is respectfully requested in view of the above amendments and the following remarks.

Claims 1, 5, 6, 9, 12, and 24 have been amended to more particularly point out and distinctly claim the subject matter of applicant's invention. Amendments to Claims 1, 5, 6, 9, 12, and 24 are supported by the specification.

New claims 26 to 35 have been added. Claims 1-35 are now in the application. New claims 26 to 35 are based on and are identical in wording to claims 2 to 11 presented above and are all dependent from amended claim 24. Claim 24 is a combination of the subject matter of claim 1 presented above and claim 24 previously added. Full support for the subject matter of claims 26 to 35 can be found in the specification as filed.

Applicant submits that the independent claims 1, 12, and 24 remaining in the application read on all species disclosed, and thus, are generic.

Thus, Applicant submits that no new matter was introduced and that no new search is required for the subject matter claimed in the new claims 26 to 35.

**Office Action**

Turning now to the Office Action in greater detail.

**Paragraph 1 (Claim Objections)**

The Examiner objected to Claims 5-6 because of informalities.

In response, claims 5-6 have been amended to overcome the informalities.

Withdrawal of the objection is respectfully requested.

**Paragraphs 2 through 5 (Claim Rejections - 35 USC § 103)**

The Examiner rejected Claims 1-8, 11-13, and 15-23 under 35 U.S.C. 103(a), as being unpatentable over Carman, et al. (U.S.P.N. 6,284,193) in view of Jacobs, et al. (U.S.P.N. 6,325,972).

Applicant traverses this rejection.

In response, Applicant respectfully submits that the currently amended claims 1 and 12 define subject matter patentably distinguished from the teachings of Carman et al. and Jacobs et al., whether taken alone or in combination.

Further, from a study of its figures and description, it is apparent that the Carman et al. reference teaches a method and apparatus for using a continuous stream of ozone containing gas to reduce the biological load on consumer products or medical equipment. In contrast, amended claims 1 and 12 now define a batch process, wherein sterilization gas is injected into the chamber, the chamber is sealed and the ozone is maintained in the chamber for a selected treatment period without ozone being added or removed. Carman et al. state that the use of Ozone in a static fashion does not provide adequate sterilization. However, as mentioned, the method of the present application does employ Ozone in a static fashion as is apparent from step (f) or amended claim 1. Carman et al. clearly state that prior art sterilization methods relying on filling the sterilization chamber with Ozone gas and exposing the materials therein to the sterilization gas without replenishing the sterilization gas are known, but not effective. Thus, Carman et al. clearly teach away from using a batch type sterilization process as disclosed and claimed in the present application.

In addition, the specific problem addressed by the present invention is one associated mainly with batch type ozone sterilization processes carried out at high levels of relative humidity. Consequently, it is respectfully submitted that a person skilled in the art, when grappling with a batch process specific problem, would not turn to a prior art continuous process, such as the Carman et al. method, in trying to solve that problem, especially not when Carman et al. specifically advise against the use of a batch type process.

In batch type sterilization processes run at high relative humidity, localized temperature differentials between the materials to be sterilized and the temperature in the sterilization chamber lead to localized condensation, especially as the sterilization chamber atmosphere approaches saturation. This condensation, however, prevents access of the sterilant, the ozone gas, to the surface of the article to be sterilized, possibly leading to unsuccessful sterilization at the location of the condensation. Furthermore, this condensation often occurs at hard to reach locations, such as in interstices of the article (for example, hinges or pivots) or in small, semi-enclosed spaces, and will often remain at those locations through successive sterilization cycles. This problem is now overcome according to the method of the present invention by adding, prior to the step of humidifying the atmosphere in the sterilization chamber, the step of equalizing the temperature of the materials in the chamber with the temperature of the surrounding atmosphere, in order to avoid those localized temperature differentials and the resulting condensation. It is respectfully submitted that neither Carman et al. nor Jacobs et al., whether taken alone or in combination teach this solution.

Applicant submits that the claims as amended define a batch gas sterilization method and apparatus using ozone as the sterilization gas and employing a temperature equalization step preceding the humidification step. In the equalization step, the temperature of any materials in the sterilization chamber is equalized with the temperature of the surrounding atmosphere in the sterilization chamber to avoid localized temperature differentials, which may lead to condensation at high levels of humidity.

The Examiner acknowledges that Carman et al. do not teach such a temperature equalization step. However, the Examiner states that the Jacobs et al. process will necessarily lead to a temperature equalization. Applicant respectfully disagrees. Although the Jacobs et al. process in one embodiment may include an air flushing step prior to the first sterilization step, that step does not necessarily lead to temperature equalization, but may actually aggravate the problem, which is to be overcome by the present invention, namely--localized temperature differences. Jacobs et al. clearly state that the air flushing step is carried out for drying of the materials to be sterilized in situations where the materials to be sterilized were previously exposed to a liquid sterilant. However, Jacobs et al. do neither teach nor even acknowledge anywhere that removing water from the surface of an object by evaporation under vacuum will result in localized cooling of the object. In order for evaporation to occur, the evaporation energy has to be supplied by the surrounding matter, in this case the object on which the water is located. This results in localized temperature differences, which will cause localized condensation at increased levels of humidity. Thus, contrary to the assertion by the Examiner, simply using an air flushing and drying step as

taught in Jacobs et al. will not necessarily lead to a temperature equalization between the materials to be sterilized and the surrounding atmosphere. Jacobs et al. do not acknowledge the fact that such localized temperature differences may occur nor would the occurrence of such temperature differences have any effect on the efficiency and effectiveness of the Jacobs et al. process, which goal it is to dry, not humidify, the sterilization atmosphere prior to and during sterilization. This is understandable, since Jacobs et al. teach a sterilization process using a liquid sterilant, not a gaseous sterilant, and in particular a process in which the aqueous sterilant solution to be effective must be concentrated. It is stated at various locations throughout the Jacobs et al. patent that it is a goal of the process to concentrate an aqueous sterilant solution in the sterilization chamber by removal of water vapour from the solution and the sterilization chamber. Thus, Jacobs et al. not only fail to teach to the art skilled person the reason and need for the temperature equalization step of the present invention, but teach a sterilization process completely unrelated to and having totally opposite goals from the process of the present invention. In the process of the present invention the sterilization chamber atmosphere must be humidified prior to addition of the ozone-containing sterilization gas, while in the process of Jacobs et al. the sterilization chamber atmosphere is dried by continually by removing water vapour through the vacuum pump. Thus, even if the processes of Carman et al. and Jacobs et al. were to be combined, the resulting method would not overcome the problem addressed by the present invention. It is furthermore respectfully submitted that a person skilled in the art grappling with the problem of localized sterilization failure due to condensation in a batch sterilization process,

would not turn to either of Carman et al. or Jacobs et al. for a solution, since both references are directed to continuous processes, not batch processes, and neither acknowledge the existence of this problem nor teach a solution thereto. Consequently, a person skilled in the art would not have any incentive to combine the teachings of the Carman et al. and Jacobs et al. processes. Moreover, even combining the Jacobs et al. process with the Carman et al. process would not result in a process as defined in the currently amended claims. Therefore, Applicant respectfully requests the Examiner to withdraw his rejection of the claims under 35 USC 103(a).

Withdrawal of the rejection is respectfully requested.

#### **Apparatus Claims**

The Applicant respectfully submits that the same arguments also apply with respect to currently amended apparatus claim 12, which now clearly includes structures used for carrying out a batch process and defines the purpose of the means for equalizing the temperature as being the prevention of condensation of water on the article due to localized temperature differentials. This is clearly opposite to the teachings of Carman et al. and, thus, distinguished from a combination of Carman et al. and Jacobs et al.

Withdrawal of the rejection is respectfully requested.

#### **Paragraph 6: Claim Rejection - 35 USC § 103**

The Examiner rejected Claims 9-10 under 35 U.S.C. 103(a) as being unpatentable over Carman, et al. (U.S.P.N. 6,284,193) in view of Jacobs, et al. (U.S.P.N. 6,325,972) as applied to Claim 1 and further in view of Shapiro (U.S.P.N. 3,719,017). It is the Examiner's opinion that it would have been obvious to the

one of ordinary skill in the art to modify the Carman et al. reference by repeating the steps of vacuuming, humidifying, supplying ozone and maintaining pressure in the chamber to completely expel air from the chamber.

Applicant traverses this rejection.

In response, Applicant respectfully disagrees with the conclusion of the Examiner. The Carman et al. process is not a batch process, but a process with continuous evacuation of the chamber and supply of sterilant, for the purpose of driving out the air surrounding any of the articles to be sterilized. Thus, the one of skill in the art would not see any need for repeating the vacuum application, humidification and ozonation steps. Moreover, since claims 9 and 10 depend from claim 1 and in view of the arguments presented above in relation to amended claim 1, Applicant respectfully submits that the subject matter of claims 9 and 10 is not rendered obvious by the teachings of Carman et al., Jacobs et al. and Shapiro, when taken alone or in combination.

Applicant respectfully requests withdrawal of the rejection of claims 9 and 10 under 35 USC 103(a).

Paragraph 7: Claim Rejection - 35 USC § 103

The Examiner rejected Claim 14 under 35 U.S.C. 103(a) as being unpatentable over Carman, et al. (U.S.P.N. 6,284,193) in view of Jacobs, et al. (U.S.P.N. 6,325,972) as applied to Claim 12 and further in view of Shapiro (U.S.P.N. 3,719,017).

Applicant traverses this rejection.

Claim 14 is directed to an apparatus as defined in claim 12, including a water reservoir (*inter alia*). In view of the amendment to claim 12, which renders that claim patentable over the combination of Carman et al. and Jacobs et al., the

Applicant believes the arguments presented above in relation to claim 12 and the Carman et al. and Jacobs et al. references also apply to claim 14. Furthermore, since amended claim 14 includes all the features of amended claim 12 as well as the additional limitations of a door for sealing the sterilization chamber, a water reservoir, and a means for controlling the temperature of the chamber, the door, the humidifier and the water reservoir, claim 14 is submitted to be more limited in scope than amended claim 12. Therefore, in view of the arguments presented above, Applicant submits that claim 14 is patentable over Carman et al. in view of Jacobs et al. and Shapiro. Thus, Applicant respectfully submits that the apparatus of claim 14 is not rendered obvious by the teachings of Carman et al., Jacobs et al. and Shapiro when taken alone or in combination.

Withdrawal of the rejection of claim 14 under 35 USC 103(a) is respectfully requested.

**Paragraph 8 (Allowable Subject Matter)**

The Examiner objects to Claims 24-25 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In response, Applicant has now rewritten claim 24 as requested by the Examiner by incorporating therein the subject matter of claim 1 as amended. Claim 25 is now dependent from amended claim 25. Consequently, claims 24 and 25 are now believed to be in allowable form. New claims 26 to 35 are also believed allowable since dependent from amended claim 25.



**New Claims**

New claims have been added and there are presently 3 independent claims and 35 claims in total pending in the application. Thus, 1 independent and 10 dependent claims were added.

**Paragraph 9 (Response to Arguments)**

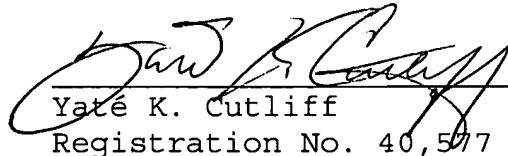
Applicant notes Examiners comments.

Review and reconsideration of the Office Action of August 10, 2005, is respectfully requested in view of the above amendments and remarks.

Applicants have correctly amended the claims to overcome the claim objections cited by the Examiner.

All claims are now in condition for allowance. Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,

  
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U.S. Application No. 10/005,786  
AMENDMENT B

Attorney Docket No.: 3648.028



CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing AMENDMENT B for U.S. Application No. 10/005,786 filed November 8, 2001, was deposited in first class U.S. mail, with sufficient postage, addressed: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **November 10, 2005**.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

  
Yaté K. Cutliff